



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/301,670	04/28/99	CHORNET	E AML/10857.23

ALAIN M LECLERC
GOUDREAU GAGE DUBO & MARTINEAU WALKER
THE STOCK EXCHANGE TOWER
800 PLACE VICTORIA SUITE 3400
MONTREAL PQ H4Z 1E9
CANADA

HM12/1106

AIR MAIL

EXAMINER	
WEBMAN, E	
ART UNIT	PAPER NUMBER

1617

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/301670

Applicant(s)

CHORNGT

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/16/01 5/16/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-16 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-16 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 7, 13, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by
Dimetris^u et al. '706.

Dimetris^u et al '706 teach hydrogels comprising Chitosan and Xanthan containing drugs or proteins (claim 1). Hydrophobic compounds such as quinidine (claim 3) and hydrophilic compounds such as enzymes (claim 4) are specified. Applicants' ^{intended use is not considered a} patentable limitation during prosecution before this agency.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 15, 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,620,705. Although

Art Unit: 1617

the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the patented claims overlap in scope.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydrogels comprising 24-40% Chitosan and 60-76% Xanthan, does not reasonably provide enablement for hydrogels comprising any percentage of ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Table 6 discloses the above cited ranges. None broader are specified.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 13, 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimetri^u~~a~~ et al. '706.

Dimetri^u~~a~~ '706 disclose hydrogels comprising Chitosan and Xanthan which have high retention yields of biological products (Abstract, column 1, lines 57-58).

Preservation of complex molecules (column 1, lines 60-61) and zero order Kinetics for Ne^eutral drugs (column 2 lines 17-18) are disclosed.

The examiner takes notice under MPEP 2144.03 that Vitamin A is a neutral compound with pharmaceutical activity.

Art Unit: 1617

It would have been obvious to one of ordinary skill to deliver Vitamin A in the vehicle of Dimetria^u et al to achieve the beneficial effect of zero order release.

NO claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) -308-4432. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) -308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) -308-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Webman/LR

October 10, 2001

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500